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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,526	11/28/2003	Anders Rosholm	45900-000830/US	7605

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HARNESS, DICKEY & PIERCE, P.L.C.
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EXAMINER

WEI, YAN-ZHEN


ART UNIT	PAPER NUMBER
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3768

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.		Applicant(s) 	
	10/722,526		ROSHOLM ET AL.	
	Examiner		Art Unit	
	Yan Wei		3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/28/2004; 5/13/2005; 9/6/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because numeral minor spelling and grammatical errors such as

Improper

in **an** 2-dimensional

has a pre-defined ...

Proper

in **a** 2-dimensional

have a pre-defined ...

A more thorough check of the abstract and appropriate corrections are required.

2. The disclosure is objected to because of numerous informalities such as:

Paragraph #	Line #	Improper
1	10	to to
15	1	the present invent
15	4	in an 2-dimensional projection image
41	5	pre-defined origo

A more thorough check of the specification and appropriate corrections are required.

Claim Objections

3. A number of claims are objected due to numerous typos and/or grammatical errors. For example,

Claims 1 and 17 are objected to because of the following informality:

"in an 2-dimensional projection image" .

The examination is conducted based on the examiner's interpretation to the phrase as "in a 2-dimensional projection image".

Appropriate corrections to all claims having such phrase are required.

Claims 2 and 18 are objected to because of the following informality:

"the **periostal** edges of the bone". The examination is conducted based on the examiner's interpretation to the phrase as "the **periosteal** edges of the bone". Appropriate corrections are required.

Claim 9 and 25 are objected to because of the following informality:

"the contours of the digital templates **is** represented as in a coordinate system with a pre-defined **origo**". The examination is conducted based on the examiner's interpretation to the phrase as "the contours of the digital templates **are** represented as in a coordinate system with a pre-defined **origin**". Appropriate corrections are required.

Claim 22 is objected to because of the following informality:

"wherein **the** comprising a digitizing device". The examination is conducted based on the examiner's interpretation to the phrase as "wherein comprising a digitizing device". Appropriate correction is required.

Claim 28 is objected to because of the following informality:

"A system according to claim **17**". As claim 27 discloses plurality of templates while claim 17 doesn't, the examination is conducted based on the examiner's interpretation to the phrase as "A system according to claim **27**". Appropriate correction is required.

Claim 30 is objected to because of the reference to Fig. 8. Claims are to be complete in themselves. Incorporation by reference to a specific figure is not acceptable for this application. See MPEP 2173.05(s).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. A number of claims are rejected under the first paragraph of 35 U.S.C. 112.

For example, claims 1 and 17 are objected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

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matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The phrase in the claims "an orientation of the digital template and a **position** orthogonal to the main bone orientation" does not define the subject matter in exact terms because a position is a point that is not able to form an orthogonal relationship with respect to a line.

The examination is conducted based on the examiner's interpretation as "an line orthogonal to the shaft axis and going through the cup center" according to applicant's description of the preferred embodiment.

Please check all claims and make necessary corrections to ensure the 35 U.S.C.112 compliance.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. A number of claims are rejected under the second paragraph of 35 U.S.C. 112. For example,

Claims 1 and 17 are objected because they recite the limitations "the relevant bone", "the template" and "the main bone orientation". There are insufficient antecedent bases for these limitations in the claims. The examiner interprets "the relevant bone"

and "the main bone" as the bone to be repaired shown in the 2D projection image, "the template" as the digital template to be fit.

The subsequent dependent claims that recite such phrases are also rejected.

Claims 2 and 18 are rejected because they recite the limitations "the main bone orientation" and "the bone". There are insufficient antecedent bases for these limitations in the claim. The examiner interprets "the bone" and "the main bone" as the bone to be repaired shown in the 2D projection image.

The subsequent dependent claims that recite such phrases are also rejected.

Claims 12 and 13 are rejected because they recite the limitations "the system". There is insufficient antecedent basis for this limitation in the claims. The examiner interprets "the system" as a computer system.

Please check all claims and make necessary corrections to ensure the 112 compliance.

8. The Examiner suggests to use "medullary" in place of "medullar".

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-2, 4-6, 10, 17-18, 20-22, 26 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by US patent #6692448 to Tanaka et al.

Tanaka et al. teach an artificial bone template selection system comprising storing devices (Column 11, lines 36-39) and prospective template selection means including steps of manually designating feature points (Column 10, lines 37-39) on the edge of medullary cavity of a femur image, such as points E and F in Fig. 1, and along the main bone orientation AC as shown by points A, B and C in Fig.1; finding the template with the corresponding feature points that conforms in shape of the contour BEFD in Fig.1 (Column 10, lines 49-51, lines 64-67 and column 11, lines 1-6); and determining an orientation OO' which is substantially orthogonal to the main bone orientation AC such that the contours of the templates fit the detected edges of the medullary space when the template is superposed on the bone image (Column 11, lines 7-13), wherein the main bone orientation AC is estimated on the basis of the periosteal edge A and the edge of medullary space B. Tanaka et al. also disclose the use of an X-ray image of femur with surrounding bone structures (Column 7, lines 16-23). Tanaka et

al. further teach that the system and method are applicable for selecting and displaying the best matching templates from plurality of templates (Column 11, lines 7-14).

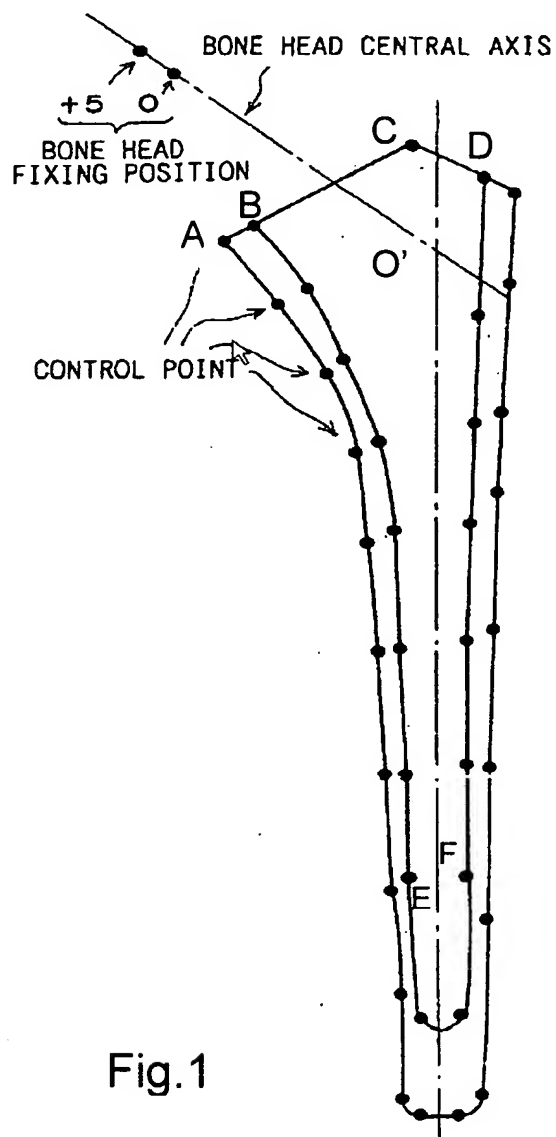


Fig.1

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claim 1-2, 4-8, 10-12, 17-18, 20-24, and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by the US Pub #2005/0054917 of Kitson.

Kitson teaches orthopedic surgery planning methods, software and systems. One of the methods employs a computer system (claim 29) comprising a display, a template database, calculating and selecting means. The method performed by the computer system comprising the steps of 1) Display an X-ray image covering the hip joint of a femur to have an implant, wherein the medullar edges of the femur show the maximum intensity (The area around numeral 94 in Fig. 4); 2) Automatically detecting the acetabulum, femoral medullar space and edges, and determining the main bone orientation (Fig 3(a), paragraph 120); 3) Determining and measuring the diameter of a femur medullary cavity by outlining the femoral canal (Fig.3(a) and paragraph 120) and using a linear scaling tool (Paragraph 111); 4) Determining the femur shaft orientation

and a line perpendicular to it (Fig. 4) ; 5) Selecting plurality of template candidates sorted via shading and displayed based on the goodness of geometrical matching, i.e. minimized the distance, between the template contour and the medullar edges of the bone for the prosthesis (Paragraph 123). Kitson further teaches the use of a digital X-ray image system (Claim 1-2).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 3 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitson as applied to claims 1 and 17 above, and further in view of US Patent #5696805 to Gaborski et al.

Kitson teaches all the elements of the current invention except for using a digital filtering technique to estimate the main bone orientation. In the same field of endeavor, Gaborski et al. teach an apparatus and method for identifying specific bone region in digital X-ray images. Gaborski et al. use a digital filtering technique to remove noise from the binarized hand image and process the image to form an estimate of the central

axis of the bones (Column 2, lines 58-62). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the teaching of Kitson and use a digital filtering technique for automatically delimiting or segmenting regions of interest (Column 3, lines 15-18).

15. Claims 9, 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitson as applied to claims 2 and 17 above, and further in view of US Patent #5360446 to Kennedy.

Kitson teaches all the elements of the current invention except for representing the template contours with x- and y- coordinates. In the same field of endeavor, Kennedy teaches an interactive digital template design system that employing the x- and y- coordinates to represent the contour of a femoral template (Column 11, lines 45-65). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Kitson's teaching and use x- and y-coordinates to represent the contour of a digital template in order to be compatible with one of the prosthesis design algorithm (Column 11, lines 65-69 and column 12, lines 1-7).

16. Claims 13-16 and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitson as applied to claims 5 and 17 above, and further in view of US Pub # 2003/0176860 of Shimura.

Kitson teaches all the elements of the current invention except for handling the expected post operational changes from the measures based on the bone and digital

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template images. In the same field of endeavor, Shimura teaches the method and the required system assuming and estimating various bone shift after operation, such as leg length differences for a femur (Paragraphs 18 and 46). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the teaching of Kiston and consider post-operation bone position changes to improve the efficiency and accuracy of the operating plan (Paragraph 11).

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Tanaka et al. (US patent #7039225) teach an artificial bone template selection system.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yan Wei whose telephone number is (571) 272-5356. The examiner can normally be reached on 9am-6:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

yw


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